

Exhibit I

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FILED
CLERK'S DIV.
CIV. 07-11033
PATRICK E. LARSON, CLERK
BY _____
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ATTORNEYS FOR DEFENDANT

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
HELENA DIVISION

THE STATE OF MONTANA,)
ex rel MIKE McGRATH,)
Attorney General,)
Plaintiff,) No.: CIV. 07-H DWM
vs.)
Judge D. NICICOU
MERCK & CO., INC.)
Defendant.)

PLEASE TAKE NOTICE that Defendant Merck & Co., Inc. ("Merck"), through undersigned counsel, hereby removes the above-captioned action from the District Court for the First Judicial District in Lewis & Clark County, Montana to the United States District Court for the District of Montana, pursuant to 28 U.S.C. §§ 1331 and 1441. In support of its removal, Defendant respectfully states as follows:

1. This action involves allegations regarding the prescription drug Vioxx®.

An MDL proceeding has been established in the United States District Court for the Eastern District of Louisiana (Fallon, J.) for coordinated pretrial proceedings of Vioxx-

related actions under 28 U.S.C. § 1407. Two other suits filed by the state attorneys general of Louisiana and Mississippi alleging similar claims against Merck are already pending in that MDL proceeding,¹ and Merck intends to seek the transfer of this action to that MDL proceeding as well.

2. On December 28, 2005 the State of Montana ("the State") commenced this action in the District Court for the First Judicial District in Lewis & Clark County, Montana, against Merck, captioned *State of Montana ex rel. McGrath v. Merck & Co., Inc.*, No. ADV-2005-899. A true and correct copy of Plaintiff's Complaint is attached as Exhibit A.

3. Merck has not been served with a copy of the Complaint ("Compl."). Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b).

4. Venue is proper in this Court pursuant to 28 U.S.C. § 89(c), because it is the "district and division embracing the place where such action is pending." *See* 28 U.S.C. § 1441(a).

5. No previous application has been made for the relief requested herein.

6. Merck will promptly (a) file a true and correct copy of this Notice of Removal with the Clerk of Court for the District Court for the First Judicial District in Lewis & Clark County, Montana in accordance with 28 U.S.C. § 1446(d); and (b) serve Plaintiff's counsel with a true and correct copy of this Notice of Removal, in accordance with 28 U.S.C. § 1446(d).

¹ The two state attorney general actions are *Foti v. Merck*, No. 05-3700 (E.D. La.) (Louisiana), and *Hood v. Merck*, No. 05-6755 (E.D. La.) (Mississippi).

I. ALLEGATIONS AND REQUESTED RELIEF

7. Plaintiff's complaint alleges that Merck violated the Montana Food, Drug, and Cosmetic Act, Mont. Code Ann. § 50-31-101, *et seq.*, because its "advertisements made false and misleading claims to doctors and the public in Montana about the effectiveness of Vioxx." (Compl. ¶ 67.) The State also alleges that Merck committed "deceit" under Mont. Code Ann. § 27-1-712 by making "suggestions of fact that Merck knew were not true" and "suppress[ing] facts about the cardiovascular dangers of Vioxx." (*Id.* ¶¶ 70-71.) Additionally, the State alleges that Merck misrepresented, omitted, and suppressed material facts about the safety and efficacy of Vioxx in violation of Montana's Unfair Trade Practices and Consumer Protection Act, Mont. Code. Ann. § 30-14-103 ("UTPCPA"). (*Id.* ¶ 74-79.) Lastly, the State alleges that Merck has been unjustly enriched due to its misleading conduct. (Compl. ¶ 81-86.)

8. The State seeks civil penalties of \$10,000 against Merck for each alleged violation of deceit under Mont. Code Ann. § 30-14-103; restitution for the State of Montana and the citizens of the State of Montana; disgorgement of alleged unjust profits from the sale of Vioxx to the citizens of the State of Montana and the State of Montana; attorneys' fees and costs; and "such other and further relief as the Court deems just, necessary, and appropriate." (Compl., Prayer for Relief.)

II. FEDERAL QUESTION JURISDICTION

9. This Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. § 1331, because the State's claims directly implicate two areas of federal law: the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, which regulates prescription drug manufacturers' public and promotional statements about prescription drugs; and federal Medicaid law, which determines both which drugs a

state must cover under its Medicaid program and the limited circumstances under which it can decline to pay for such drugs. *See* 42 U.S.C. §§ 1396r-8(d)(1)(B), (d)(4). Thus, this action may be removed to this Court pursuant to 28 U.S.C. § 1441.

10. The Supreme Court has recognized that federal question jurisdiction exists over claims that are asserted under state law if the state law claims implicate substantial federal questions. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 125 S. Ct. 2363, 2369 (2005). *See also Hopkins v. Walker*, 244 U.S. 486, 490-491 (1917); *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1025 (N.D. Cal. 2005).

11. As the Supreme Court explained in *Grable*, the test for whether a federal court should hear a case under this doctrine is not whether the federal statute provides a parallel private right of action, but whether the “state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” 125 S. Ct. at 2368. In *Grable*, the Supreme Court concluded that federal question jurisdiction existed because the plaintiff’s state law claim was premised on the failure of a government agency to fulfill its responsibilities as defined by federal law. Thus, federal question jurisdiction existed because the meaning of the federal law was an essential element of the state law claim. *Id.* The same is true here.

12. First, the claims in this case are implicitly premised upon alleged violations of the *federal* Food, Drug & Cosmetic Act (“FDCA”) – namely that Merck illegally promoted an unsafe drug for public use and failed to warn doctors, state regulators, and consumers of risks in violation of FDCA rules and regulations.

13. Under the FDCA, the Food and Drug Administration (“FDA”) is tasked with approving drugs for human use and determining the necessary warnings manufacturers must include with their products. 21 U.S.C. § 393(b). The FDCA charges the FDA to ensure that “drugs are safe and effective” for their intended uses, *id.* § 393(b)(2)(B), in part by “promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products.” *Id.* § 393(b)(1). The FDA is vested with the authority to promulgate regulations to enforce the FDCA, which are codified in the Code of Federal Regulations, 21 C.F.R. § 200 *et. seq.*; 21 U.S.C. § 371(a).

14. To accomplish this mandate, the FDA maintains a Center for Drug Evaluation and Research (“CDER”). The CDER oversees the drug companies’ development, testing and research, and manufacture of drugs. The staff of approximately 1,800 examines clinical and other testing data generated by drug companies to assess a drug’s benefits against its risks and to make an approval decision. The CDER also regulates prescription drug advertising, including the Package Inserts that outline benefit and risk information, and monitors marketed drugs for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. Under federal law, even claims in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4) (2005).

15. For these reasons, Plaintiff’s allegations related to Merck’s promotion of Vioxx will necessarily require the Court to interpret the meaning of the FDCA and its attendant regulations. This is evident from Plaintiff’s complaint, which includes extensive quotes from a letter that the FDA sent Merck regarding the contents of its

marketing materials for Vioxx (Compl. ¶ 36), and several allegations regarding Merck's interactions with the FDA over Vioxx labeling. (See *id.* ¶¶ 38-39.)

16. Second, Plaintiff's claim for recovery of monies spent by the State of Montana on Vioxx necessarily implicates federal laws and regulations related to Medicaid.²

17. Plaintiff's refund claims on behalf of the state of Montana implicate substantial questions of federal law under the federal Medicaid statute because they depend on the interpretation and application of federal statutory provisions that govern what can be included in or rejected from State Medicaid formularies, including Montana's, and because federal funds comprise the majority of Montana Medicaid Program's funds – the money at issue in this lawsuit.³

18. The federal Medicaid program authorizes federal money grants to states to provide medical assistance to low-income individuals. 42 U.S.C. § 1396 *et seq.*; 42 C.F.R. § 430.10 *et seq.* “Although participation in the program is voluntary,

² While plaintiff has assiduously avoided using the word “Medicaid” in the Complaint, the state attorney general's request for reimbursement of funds spent by the *state* for Vioxx is obviously a request for recovery of Medicaid funds, as other state attorney generals' similar complaints readily admit. See Compl., *Foti v. Merck*, No. 05-3700 (E.D. La.) (Louisiana) (seeking damages, in part, for the purchase price paid by the State of Louisiana's Medicaid program for Vioxx prescriptions); Compl., *Hood v. Merck*, No. 05-6755 (E.D. La) (Mississippi) (seeking damages, in part, for the purchase price paid by the State of Mississippi's Medicaid program for Vioxx prescriptions); Compl., *Alaska v. Merck*, No. 3:06-CV-00018 (TMB) (D. Alaska) (seeking damages primarily for the purchase price paid by the State of Alaska's Medicaid program for Vioxx prescriptions).

³ For fiscal year 2004 (October 1, 2003 to September 30, 2004), for example, federal funds accounted for 72.85% of Montana's Medicaid financing. See *Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the State Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2003 Through September 30, 2004*, 67 Fed. Reg. 69,223, 69,224, Nov. 15, 2002, available at <http://www.aspe.hhs.gov/health/fmap04.htm>.

participating States must comply with certain requirements imposed by the Medicaid Act . . . and regulations promulgated by the Secretary of Health and Human Services.” *Wilder v. Va. Hosp. Ass’n*, 496 U.S. 498, 502 (1990). In Montana, the Medicaid program is administered by the Department of Public Health and Human Services. *See* <http://www.dphhs.mt.gov/programsservices/medicaid.shtml>; 42 C.F.R. § 431.10(b)(1) (requiring states to designate “a single State agency . . . to administer or supervise the administration of the [Medicaid] plan”).

19. Federal law expressly requires states, subject to certain narrow exceptions, to reimburse FDA-approved prescription drugs of any manufacturer that has entered into and complies with a rebate agreement with the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(d)(4)(B). Thus, Montana is required under federal law to reimburse companies for drugs, such as Vioxx, if the manufacturer complies with federal requirements.

20. The only time a state can exclude from its formulary a covered outpatient drug subject to a rebate agreement is “with respect to the treatment of a specific disease or condition for an identified population . . . if, based on the drug’s labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.” 42 U.S.C. § 1396r-8(d)(4)(C). But even in such a situation, a state cannot deny coverage altogether; rather, it must condition such reimbursement on prior authorization, meaning that the state may require that it approve the drug’s dispensation before it is dispensed. *Id.* § 1396r-8(d)(4)(D). And even a decision to require prior authorization must satisfy federally

mandated requirements. *Id.* §§ 1396r-8(d)(4)(E), (d)(5). Thus, every step a state takes with regard to coverage of an FDA-approved drug is subject to strict federal mandates.

21. In short, because the Montana Medicaid program operates within this overarching federal regulatory framework, Plaintiff's claims alleging that Merck's conduct concerning Vioxx caused the State of Montana to spend money on Vioxx for which the state now seeks a refund necessarily turns on substantial questions of federal Medicaid law.

22. Other courts have applied *Grable* and recognized that federal jurisdiction exists over actions, like this one, in which plaintiffs' state law claims are premised on violations of the FDCA and cases in which plaintiffs seek reimbursement of Medicaid expenditures. For example, in *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the court asserted federal question jurisdiction over state-law claims brought by the state of Louisiana involving a manufacturer's marketing of a prescription drug and the state of Louisiana's payments for that drug under Medicaid, finding that the state attorney general's claims involved "a core of substantial issues [that were] federally oriented." *Id.* at 172-73.

23. Similarly, in a recent case involving Medicaid drug pricing, the court in *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022 (N.D. Cal. 2005), held that federal jurisdiction was proper under *Grable* because the plaintiff's state law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. In concluding that the Medicaid drug pricing issues merited federal jurisdiction, the court observed that one measure of evaluating substantiality is "the importance of the federal issue." *Id.* at 1027. The court noted that "[u]nder this approach, the following issues have been

found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme." *Id.*

24. As set forth above, Plaintiff's claims here implicate two complex federal regulatory schemes: the federal FDCA and federal Medicaid law. Accordingly, as in *Grable, Zyprexa, and Astra USA*, Plaintiff's allegations will necessarily require the Court to address substantial questions of federal law, and the Court therefore has federal question jurisdiction over this matter.

25. WHEREFORE, Defendant gives notice of the removal of the above-captioned action now pending in the District Court of the First Judicial District, Lewis & Clark County, Montana, captioned *The State of Montana, ex rel Mike McGrath, Attorney General, v. Merck & Co., Inc., Cause No. ADV-2005-899*, to this Court.

Dated this 1st day of March, 2006.



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ATTORNEYS FOR DEFENDANT

Exhibit J

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FILED IN UNITED STATES DISTRICT
COURT, DISTRICT OF UTAH

MAY 18 2006
BY MARKUS B. ZIMMER, CLERK
DEPUTY CLERK

Attorneys for Defendant Merck & Co., Inc.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH
NORTHERN DIVISION

THE STATE OF UTAH,

Plaintiff,

vs.

MERCK & CO., INC.,

Defendants.

**NOTICE OF REMOVAL OF
DEFENDANT MERCK & CO., INC.**

Judge Dee Benson
DECK TYPE: Civil
DATE STAMP: 05/18/2006 @ 11:42:32
CASE NUMBER: 2:06CV00406 DB

TO THE CLERK OF THE ABOVE-ENTITLED COURT:

NOTICE OF REMOVAL

Defendant Merck & Co., Inc. ("Merck"), through undersigned counsel, hereby removes the above-captioned action from the Third Judicial District Court of Salt Lake County, Utah, to the United States District Court for the District of Utah, pursuant to 28 U.S.C. §§ 1331 and 1441.

In support of its removal, defendant respectfully states as follows:

1. This action involves allegations regarding the prescription drug Vioxx®. An MDL proceeding has been established in the United States District Court for the Eastern District of Louisiana (Fallon, J.) for coordinated pretrial proceedings of Vioxx-related actions under 28

U.S.C. § 1407. Two other suits filed by the state attorneys general of Louisiana and Mississippi alleging similar claims against Merck are already pending in that MDL proceeding,¹ and two other district courts have stayed suits by the attorneys general of Alaska and Montana pending transfer to the MDL. *See Montana v. Merck & Co., Inc.*, No. CV-06-07-H-DWM (D. Mont. May 12, 2006) (attached as Ex. A); *Alaska v. Merck & Co., Inc.*, Case No. 3:06-cv-0018-TMB (D. Alaska Mar. 6, 2006) (attached as Ex. B). Merck likewise intends to seek the transfer of this action to that MDL as well.

2. On April 28, 2006, the State of Utah commenced this action in the Third Judicial District Court of Salt Lake County, Utah, against Merck, captioned *The State of Utah vs. Merck & Co., Inc.*, Civil No. 060907140. A true and correct copy of plaintiff's Complaint ("Compl.") is attached as Exhibit C. Merck was served with a copy of the complaint on May 10, 2006. Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1441(a).

3. Venue is proper in this Court pursuant to 28 U.S.C. § 125(2), because it is the "district and division embracing the place where such action is pending." *See* 28 U.S.C. § 1441(a).

4. No previous application has been made for the relief requested herein.

5. Merck will promptly (a) file a true and correct copy of this Notice of Removal with the Clerk of Court for the Third Judicial District Court of Salt Lake County, Utah in accordance with 28 U.S.C. § 1446(d); and (b) serve plaintiff's counsel with a true and correct copy of this Notice of Removal, in accordance with 28 U.S.C. § 1446(d).

¹ The two state attorney general actions are *Foti v. Merck & Co., Inc.*, No. 05-3700 (E.D. La.) (Louisiana), and *Hood v. Merck & Co., Inc.*, No. 05-6755 (E.D. La.) (Mississippi).

6. Plaintiff's eight-count complaint alleges that Merck violated Utah's False Claims Act of the Utah Health Code, Utah Code Annotated §§ 26-20-3, 26-20-7, by making "false statements or false representations to the State and its agencies in seeking inclusion and payment [for Vioxx] under the Utah Medicaid Program," and because "the documentation given by [Merck] to the State regarding the safety and efficacy of Vioxx for inclusion and payment under the Medicaid Program was falsified or altered with intent to deceive[.]" (Compl. ¶ 67 (quotation marks omitted).) In addition, plaintiff claims that Merck committed common law violations of failure to warn, design defect, fraud and negligent misrepresentation, negligence and breach of express and implied warranty, all premised on the allegation that Merck's "assertions to the FDA, the State of Utah, physicians and the general public regarding Vioxx contained false representations as to the safety of Vioxx and its defective design." (*Id.* ¶ 38.) Plaintiff moreover alleges a negligence *per se* claim, stating that Merck "failed to meet the standard of care set by" several federal Food and Drug Administration ("FDA") regulations. (*Id.* ¶ 63.) With regard to these latter common-law based allegations, the State contends that it paid and will continue to pay for medical services benefits as a result of state Medicaid beneficiaries being harmed by their ingestion of Vioxx. (*Id.* ¶ 19 ("As a result of ingesting Vioxx, Utah Medicaid patients suffered serious health effects now requiring further and more extensive medical treatment and provision of other health-related services. . . . [Thus Plaintiff] has . . . suffered and will continue to suffer additional financial loss in the care of those Medicaid recipients who consumed prescriptions which were ineffective, unsafe and actively harmful.'").)

7. Plaintiff seeks compensatory damages for benefits paid for "past, present and future medical expenses" for the allegedly Vioxx-related injuries of Utah Medicaid beneficiaries

and for “the cost of all Vioxx prescriptions paid by the Utah Medicaid Program;” civil penalties and “costs of enforcement pursuant to [the State’s False Claims Act, Utah Code Annotated] § 26-20-9.5”; punitive and exemplary damages; and “such other and further relief as may be justified and which [the State] may be entitled to by law including, but not limited to, all court costs, witness fees and deposition fees.” (Compl., Prayer for Relief.)

8. This Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. § 1331, because the State’s claims directly implicate two areas of federal law: the Food, Drug & Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, which regulates prescription drug manufacturers’ public and promotional statements about prescription drugs; and federal Medicaid law, which determines both which drugs a state must cover under its Medicaid program and the limited circumstances under which it can decline to pay for such drugs. *See* 42 U.S.C. §§ 1396r-8(d)(1)(B), (d)(4). Thus, this action may be removed to this Court pursuant to 28 U.S.C. § 1441.

9. The Supreme Court has recognized that federal question jurisdiction exists over claims that are asserted under state law if the state law claims implicate substantial federal questions. *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 125 S. Ct. 2363, 2368-69 (2005); *Hopkins v. Walker*, 244 U.S. 486, 490-91 (1917); *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1025 (N.D. Cal. 2005).

10. As the Supreme Court explained in *Grable*, the test for whether a federal court should hear a case under this doctrine is not whether the federal statute provides a parallel private right of action, but whether the “state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any

congressionally approved balance of federal and state judicial responsibilities.” 125 S. Ct. at 2368. In *Grable*, the Supreme Court concluded that federal question jurisdiction existed because the plaintiff’s state law claim was premised on the failure of a government agency to fulfill its responsibilities as defined by federal law. Accordingly, the interpretation of federal law was essential to resolving the state law claim. *Id.* The same is true here.

11. *First*, the claims in this case are implicitly and explicitly premised upon alleged violations of the *federal* Food, Drug & Cosmetic Act (“FDCA”), specifically, that Merck illegally promoted an unsafe drug for public use and failed to warn doctors and state regulators of risks in violation of FDCA rules and regulations.

12. Under the FDCA, the FDA is tasked with approving drugs for human use and determining the necessary warning manufacturers must include with their products. 21 U.S.C. § 393(b). The FDCA charges the FDA to ensure that “drugs are safe and effective” for their intended uses, *id.* § 393(b)(1)(B), in part by “promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products.” *Id.* § 393(b)(1). The FDA is vested with the authority to promulgate regulations to enforce the FDCA, which are codified in the Code of Federal Regulations, 21 C.F.R. § 200 *et seq.*; 21 U.S.C. § 371(a).

13. To accomplish this mandate, the FDA maintains a Center for Drug Evaluation and Research (“CDER”). The CDER oversees the drug companies’ development, testing and research, and manufacture of drugs. The staff of approximately 1,800 examines clinical and other testing data generated by drug companies to assess a drug’s benefits against its risks and to make an approval decision. In addition to regulating prescription drug advertising generally, the CDER also oversees the Package Inserts that outline benefit and risk information, and monitors

marketed drugs for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. Indeed, under federal law even claims in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4).

14. The centrality of federal food and drug law to the allegations at issue in this matter are evidenced by plaintiff's own complaint, which repeatedly cites the FDA's oversight of the highly regulated representations at issue in the case. (*See, e.g.*, Compl. ¶ 16 (recognizing that the FDA "enforces federal statutes and regulations that require product safety disclosures to be truthful, fair and balanced"); *id.* ¶ 7 (noting FDA approval of Vioxx and its relationship to the ability to market Vioxx); *id.* ¶ 16 (citing a letter that the FDA sent Merck regarding the contents of its marketing materials for Vioxx) *id.* ¶ 63 (listing various FDA regulations regarding the drug approval and labeling).)

15. **Second**, plaintiff's claim for recovery of monies spent by the State of Montana on Vioxx necessarily implicates federal laws and regulations related to Medicaid because it depends on the interpretation and application of federal statutory provisions that govern what can be included in or rejected from state Medicaid formularies, including Utah's. In addition, federal funds comprise the majority of the funds at issue in this lawsuit, *i.e.*, money spent for Vioxx under the Utah Medicaid Program, and any health benefits that the State of Utah has paid or will pay as a result of alleged Vioxx-related injuries.²

² For fiscal year 2004 (October 1, 2003 to September 30, 2004), for example, federal funds accounted for 71.72% of Utah's Medicaid financing. *See Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the State Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2003 Through September 30, 2004*, 67 Fed. Reg. 69,223, 69,224, Nov. 15, 2002, available at <http://www.aspe.hhs.gov/health/fmap04.htm>.

17. The federal Medicaid program authorizes federal money grants to states to provide medical assistance to low-income individuals. 42 U.S.C. § 1396 *et seq.*; 42 C.F.R. § 430.10 *et seq.* “Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the [Medicaid] Act and regulations promulgated by the Secretary of Health and Human Services.” *Wilder v. Va. Hosp. Ass’n*, 496 U.S. 498, 502 (1990). *See also Westside Mothers v. Haveman*, 289 F.3d 852, 858 (6th Cir. 2002) (“the conditions imposed by the federal government pursuant to statute upon states participating in Medicaid and similar programs are not merely contract provisions; they are federal laws”). In Utah, the Medicaid program is administered by the Utah State Department of Health, who is required under federal law, 42 U.S.C. § 1396a, to submit a Medicaid plan which attests to the state’s compliance with federal statutes and regulations. *See* 42 C.F.R. § 430.10 (“The state plan is a comprehensive written statement submitted by the [state Medicaid] agency . . . giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances”); Utah Dep’t of Health, State Plan Under Title XIX of the Social Security Act: Medical Assistance Program § 1 (Aug. 1991), *available at* http://health.utah.gov/medicaid/st_plan/Section1.pdf (Submitting Utah’s state Medicaid plan to the federal government wherein the state “agrees to administer the [Mediciad] program in accordance with . . . all applicable Federal regulations and other official issuances”). Moreover, federal law mandates both the eligibility requirements for recipients of medical assistance and the types of medical services which must be provided if a state chooses to administer a Medicaid program. 42 U.S.C. § 1396d. *See also Coe v. Hooker*, 406 F. Supp. 1072, 1079 (D.N.H. 1976) (Under the Medicaid program, the federal government “will share

with the states the cost of any medical service offered in the state programs so long as the service comes within any of the 17 enumerated categories of medical care" in § 1396d.)

18. In addition, federal law expressly requires states, subject to certain narrow exceptions, to reimburse FDA-approved prescription drugs of any manufacturer that has entered into and complies with a rebate agreement with the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(d)(4)(B). Thus, Utah is required under federal law to reimburse companies like Merck for the drugs that it reimburses under its state program if the manufacturer has complied with federal requirements.

19. Indeed, the sole time that a state can exclude from its formulary an outpatient drug that is covered by a federal rebate agreement is "with respect to the treatment of a specific disease or condition for an identified population . . . only if, based on the drug's labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion." 42 U.S.C. § 1396r-8(d)(4)(C). But even in such a situation, a state cannot deny coverage altogether; rather, a state must condition such reimbursement on prior authorization, meaning that the state may require that it approve reimbursement before the drug is dispensed. *Id.* § 1396r-8(d)(4)(D). And even a decision to require prior authorization must satisfy federally mandated requirements. *Id.* §§ 1396r-8(d)(4)(E), (d)(5). Thus, every step a state takes with regard to coverage of an FDA-approved drug is subject to strict federal mandates.

20. To summarize, because Utah's Medicaid program operates within this overarching federal statutory and regulatory framework, plaintiff's claims alleging that Merck's

conduct concerning Vioxx caused the State of Utah to spend money on Vioxx and allegedly Vioxx-related injuries necessarily turns on substantial questions of federal Medicaid law.

21. Other courts have applied *Grable* and recognized that federal jurisdiction exists over actions, like this one, in which plaintiffs' state law claims are premised on violations of the FDCA and cases in which plaintiffs seek reimbursement of Medicaid expenditures. For example, in *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the court asserted federal question jurisdiction over state-law claims brought by the state of Louisiana involving a manufacturer's marketing of a prescription drug and the state of Louisiana's payments for that drug under Medicaid, finding that state attorney general's claims involved "a core of substantial issues [that were] federally oriented." *Id.* at 172-73.

22. Likewise, in a recent case involving Medicaid drug pricing, the court in *County of Santa Clara*, held that federal jurisdiction was proper under *Grable* because the plaintiff's state law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. In concluding that the Medicaid drug pricing issues merited federal jurisdiction, the court observed that one measure of evaluating substantiality is "the importance of the federal issue," and noted that "[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme." 401 F. Supp. 2d at 1027.

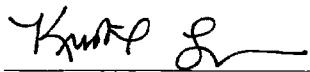
23. In short, plaintiff's claims here implicate two complex federal regulatory schemes: the federal FDCA and federal Medicaid law. Accordingly, as in *Grable*, *Zyprexa*, and

Astra USA, plaintiff's allegations will necessarily require the Court to address substantial questions of federal law, and the Court therefore has federal question jurisdiction over this matter.

24. WHEREFORE, Merck gives notice of the removal of the above-captioned action now pending in the Third Judicial District Court of Salt Lake County, Utah, captioned *The State of Utah vs. Merck & Co., Inc.*, Civil No. 060907140, to this Court.

DATED this 18 day of May, 2006.

RAY QUINNEY & NEBEKER P.C.



Rick L. Rose
Kristine M. Larsen
Attorneys for Defendant Merck & Co., Inc.

Exhibit K

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action Number:

JAMES FRANKLIN on behalf of the
STATE OF COLORADO

Plaintiffs,

v.

MERCK & CO, INC.

Defendant.

NOTICE OF REMOVAL OF DEFENDANT MERCK & CO., INC.

PLEASE TAKE NOTICE that Defendant Merck & Co., Inc. ("Merck"), through undersigned counsel, hereby removes the above-captioned action from the District Court, County of Denver, Colorado, to the United States District Court for the District of Colorado, pursuant to 28 U.S.C. §§ 1331 and 1441. In support of its removal, defendant respectfully states as follows:

1. This action involves allegations regarding the prescription drug Vioxx®. An MDL proceeding has been established in the United States District Court for the Eastern District of Louisiana (Fallon, J.) for coordinated pretrial proceedings of Vioxx-related actions pursuant to 28 U.S.C. § 1407. Four other suits regarding state Medicaid payments for Vioxx have been filed in Louisiana, Mississippi, Alaska, and Montana and are already pending in that MDL

proceeding,¹ and a fifth Medicaid suit about state payments for Vioxx in Utah is on its way to join these suits. *See Conditional Transfer Order No. 54* (J.P.M.L. June 23, 2006) (transferring Utah matter to MDL) (attached as Exhibit A). Because the subject matter of this suit, which involves Medicaid payments by the State of Colorado for the drug Vioxx, is the same as the five suits already in, or en route to, the MDL proceeding, Merck likewise will seek the transfer of this action to that MDL.

2. On September 29, 2006, Colorado taxpayer James Franklin commenced this action in the District Court, County of Denver, Colorado, purportedly on behalf of the State of Colorado, against Merck, captioned *James Franklin ex rel. State of Colorado v. Merck & Co., Inc.*, No. 2006CV10485. A true and correct copy of plaintiff's Complaint ("Compl.") is attached as Exhibit B. Merck has not been served with a copy of the complaint. Accordingly, this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b).

3. Venue is proper in this Court pursuant to 28 U.S.C. § 85, because it is the "district and division embracing the place where such action is pending." *See* 28 U.S.C. § 1441(a).

4. No previous application has been made for the relief requested herein.

5. Merck will promptly (a) file a Notice of Filing Notice of Removal, along with a true and correct copy of this Notice of Removal, with the Clerk of Court for the District Court, County of Denver, Colorado in accordance with 28 U.S.C. § 1446(d); and (b) serve plaintiff's counsel with a true and correct copy of this Notice of Removal, in accordance with 28 U.S.C. § 1446(d).

¹ The four Medicaid actions in the MDL are *Foti v. Merck & Co., Inc.*, No. 05-3700 (E.D. La.) (Louisiana), and *Hood v. Merck & Co., Inc.*, No. 05-6755 (E.D. La.) (Mississippi), *Alaska v.*

6. Merck is the only defendant in this action. Therefore, Merck need not obtain the consent of any party to remove this action.

7. As required by 28 U.S.C. § 1446(a), attached hereto as Exhibits B-E are true and accurate copies of all process, pleadings, motions, orders and other papers in the state court action.

8. A Civil Cover Sheet and Supplemental Civil Cover sheet are also attached, consistent with Local Rule, Appendix B.

9. As required by Appendix C of the Local Rules, Merck includes in its e-mail communication to the Court appropriate credit card information for the payment of \$350 to be used as the filing fee for this Notice of Removal.

10. Plaintiff's single-count complaint alleges that Merck "committed actual fraud by making material misrepresentations, which were false, knowing that such material representations were false and/or with reckless disregard for the truth or falsity of the material representations, with the intent that the State of Colorado would rely on such material representations when listing [Vioxx] as approved for payment/reimbursement and in paying for the drug." (Compl. ¶ 49.) In the alternative, plaintiff alleges that Merck "knowingly omitted material information . . . with the intent that the State of Colorado would rely on [Merck's] misrepresentations." (*Id.* ¶ 50.)

11. Plaintiff seeks "disgorgement to the State of Colorado of millions of dollars of state controlled funds used to purchase Vioxx through the Medicaid program and for attorneys'

Merck & Co., Inc., No. 06-3132 (E.D. La.) (Alaska), and *Montana v. Merck & Co., Inc.*, No. 06-4302 (E.D. La.) (Montana).

fees, interest and costs and such other and further relief as the Court deems just and proper.” (*Id.*, Prayer for Relief.)

12. This Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. § 1331, because Franklin’s claims directly implicate two areas of federal law: the Federal Food, Drug & Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, which regulates prescription drug manufacturers’ public and promotional statements about prescription drugs; and federal Medicaid law, which determines both which drugs a state must cover under its Medicaid program and the limited circumstances under which it can decline to pay for such drugs. *See* 42 U.S.C. §§ 1396r-8(d)(1)(B), (d)(4). Thus, this action may be removed to this Court pursuant to 28 U.S.C. § 1441.

13. The Supreme Court has recognized that federal question jurisdiction exists over claims that are asserted under state law if the state law claims implicate substantial federal questions. *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 314-15 (2005); *Hopkins v. Walker*, 244 U.S. 486, 490-91 (1917); *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1025 (N.D. Cal. 2005).

14. As the Supreme Court explained in *Grable*, the test for whether a federal court should hear a case under this doctrine is not whether the federal statute provides a parallel private right of action, but whether the “state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” 545 U.S. at 314. In *Grable*, the Supreme Court concluded that federal question jurisdiction existed because the plaintiff’s state law claim was premised on the failure of a government agency to fulfill its

responsibilities as defined by federal law. Accordingly, the interpretation of federal law was essential to resolving the state law claim. *Id.* The same is true here.

15. *First*, the claim in this case is implicitly and explicitly premised upon alleged violations of the *federal* Food, Drug & Cosmetic Act (“FDCA”), specifically, that Merck illegally promoted an unsafe drug for public use and failed to warn doctors and state regulators of risks in violation of FDCA rules and regulations.

16. Under the FDCA, the FDA is tasked with approving drugs for human use and determining the necessary warnings manufacturers must include with their products. 21 U.S.C. § 393(b). The FDCA charges the FDA to ensure that “drugs are safe and effective” for their intended uses, *id.* § 393(b)(1)(B), in part by “promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products.” *Id.* § 393(b)(1). The FDA is vested with the authority to promulgate regulations to enforce the FDCA, which are codified in the Code of Federal Regulations, 21 C.F.R. § 200 *et seq.*; 21 U.S.C. § 371(a).

17. To accomplish this mandate, the FDA maintains a Center for Drug Evaluation and Research (“CDER”). The CDER oversees the drug companies’ development, testing and research, and manufacture of drugs. The staff of approximately 1,800 examines clinical and other testing data generated by drug companies to assess a drug’s benefits against its risks and to make an approval decision. In addition to regulating prescription drug advertising generally, the CDER also oversees the Package Inserts that outline benefit and risk information, and monitors marketed drugs for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. Indeed, under federal law even claims in

promotional labeling or advertising must be consistent with approved labeling.

21 C.F.R. § 202.1(e)(4).

18. The centrality of federal food and drug law to the allegations at issue in this matter is evidenced by plaintiff's own complaint, which repeatedly cites the FDA's oversight of the highly regulated representations at issue in the case. (See, e.g., Compl. ¶ 11 (noting FDA approval of Vioxx and its relationship to the ability to market Vioxx); *id.* ¶¶ 30-32 (citing a letter that the FDA sent Merck regarding the contents of its marketing materials for Vioxx).)

19. **Second**, plaintiff's claim for recovery of monies spent by the State of Colorado on Vioxx necessarily implicates federal laws and regulations related to Medicaid because it depends on the interpretation and application of federal statutory provisions that govern what can be included in or rejected from state Medicaid formularies, including Colorado's. In addition, federal funds comprise half of the funds at issue in this lawsuit, *i.e.*, money spent for Vioxx under the Colorado Medicaid Program, and any health benefits that the State of Colorado has paid or will pay as a result of alleged Vioxx-related injuries among Medicaid recipients.²

20. The federal Medicaid program authorizes federal money grants to states to provide medical assistance to low-income individuals. 42 U.S.C. § 1396 *et seq.*; 42 C.F.R. § 430.10 *et seq.* “Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Medicaid Act . . . and regulations promulgated by the Secretary of Health and Human Services” *Wilder v. Va. Hosp. Ass'n*,

² For fiscal year 2004 (October 1, 2003 to September 30, 2004), for example, federal funds accounted for 50% of Colorado's Medicaid financing. *See Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the State Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2003 Through September 30, 2004*, 67 Fed. Reg. 69,223, 69,224 (Nov. 15, 2002).

496 U.S. 498, 502 (1990). *See also Westside Mothers v. Haveman*, 289 F.3d 852, 858 (6th Cir. 2002) (“the conditions imposed by the federal government pursuant to statute upon states participating in Medicaid and similar programs are not merely contract provisions; they are federal laws”). In Colorado, the Medicaid program is administered by the Colorado Department of Health Care Policy and Financing, which is required under federal law, 42 U.S.C. § 1396a, to submit a Medicaid plan which attests to the state’s compliance with federal statutes and regulations. *See 42 C.F.R. § 430.10* (“The state plan is a comprehensive written statement submitted by the [state Medicaid] agency . . . giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances . . .”); Colorado State Plan Under Title XIX of the Social Security Act: Medical Assistance Program § 1 (Nov. 2001), *available at* http://www.cms.hhs.gov/medicaid/stateplans/State_Data/CO/1.0/X_001.pdf (designating Colorado Department of Health Care Policy and Financing as the state agency to administer or supervise the administration of the Medicaid program under federal Title XIX of the Social Security Act). Moreover, federal law mandates both the eligibility requirements for recipients of medical assistance and the types of medical services which must be provided if a state chooses to administer a Medicaid program. 42 U.S.C. § 1396d. *See also Coe v. Hooker*, 406 F. Supp. 1072, 1079 (D.N.H. 1976) (Under the Medicaid program, the federal government “will share with the states the cost of any medical service offered in the state programs so long as the service comes within any of the seventeen enumerated categories of medical care” in § 1396d.)

21. In addition, federal law expressly requires states, subject to certain narrow exceptions, to reimburse FDA-approved prescription drugs of any manufacturer that has entered

into and complies with a rebate agreement with the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(d)(4)(B). Thus, under federal law, Colorado must reimburse pharmacies for drugs covered by a federal rebate agreement.

22. Indeed, the sole time that a state can exclude from its formulary an outpatient drug that is covered by a federal rebate agreement is “with respect to the treatment of a specific disease or condition for an identified population . . . only if, based on the drug’s labeling . . . the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.” 42 U.S.C. § 1396r-8(d)(4)(C). But even in such a situation, a state cannot deny coverage altogether; rather, a state must condition such reimbursement on prior authorization, meaning that the state may require that it approve reimbursement before the drug is dispensed. *Id.* § 1396r-8(d)(4)(D). And even a decision to require prior authorization must satisfy federally mandated requirements. *Id.* §§ 1396r-8(d)(4)(E), (d)(5). Thus, every step a state takes with regard to coverage of an FDA-approved drug is subject to strict federal mandates.

23. To summarize, because Colorado’s Medicaid program operates within this overarching federal statutory and regulatory framework, plaintiff’s claims alleging that Merck’s conduct concerning Vioxx caused the State of Colorado to spend money on Vioxx and allegedly Vioxx-related injuries necessarily turns on substantial questions of federal Medicaid law.

24. Other courts have recognized that federal jurisdiction exists under *Grable* over actions, like this one, in which plaintiffs’ state law claims are premised on violations of the FDCA and cases in which plaintiffs seek reimbursement of Medicaid expenditures. For example,

in *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the court asserted federal question jurisdiction over state-law claims brought by the state of Louisiana involving a manufacturer's marketing of a prescription drug and the state of Louisiana's payments for that drug under Medicaid, finding that the state attorney general's claims involved "a core of substantial issues [that were] federally oriented." *Id.* at 172-73.

25. Likewise, in a recent case involving Medicaid drug pricing, the court in *County of Santa Clara*, held that federal jurisdiction was proper under *Grable* because the plaintiff's state law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022, 1031 (N.D. Cal. 2005). In concluding that the Medicaid drug pricing issues merited federal jurisdiction, the court observed that one measure of evaluating substantiality is "the importance of the federal issue," and noted that "[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme." *Id.* at 1027.

26. In short, plaintiff's claims here implicate two complex federal regulatory schemes: the federal FDCA and federal Medicaid law. Accordingly, as in *Grable*, *Zyprexa*, and *Astra USA*, plaintiff's allegations will necessarily require the Court to address substantial questions of federal law, and the Court therefore has federal question jurisdiction over this matter.

WHEREFORE, Merck gives notice of the removal of the above-captioned action now pending in the District Court, County of Denver, Colorado, *James Franklin ex rel. State of Colorado v. Merck & Co., Inc.*, No. 2006CV10485, to this Court.

Dated: October 27, 2006

Respectfully submitted,

s/ Andrew H. Myers

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